

U.S.S.N. 10/688,305  
Filed: October 17, 2003  
AMENDMENT

### Remarks

#### Restriction Requirement

In the Restriction Requirement mailed February 24, 2006, the Examiner divided the claims into three (3) groups:

Group I, claims 1-12, drawn to a method for making a biological matrix;

Group II, claims 13-17 and 23, drawn to a method for augmenting a tissue defect; and

Group III, claims 18-22 and 24-33, drawn to a biological matrix.

It is noted that the examiner has acknowledge that upon allowance of the claims of group III, the remaining claims if amended to incorporate the same limitations, will be rejoined with the elected claims.

#### Rejections under 35 U.S.C. 102

Claims 18-22, 24, 25, 28 and 33 were rejected under 35 U.S.C. 102(b) as disclosed by U.S. patent No. 5,716,404 to Vacanti, et al. ("the '404 patent"). Claims 18, 19, 21, 22, 24, 25, 28 and 33 were rejected under 35 U.S.C. 102(b) as disclosed by U.S. Patent No. 5,885,610 to Vacanti, et al. ("the '610 patent"). These rejections are respectfully traversed.

Original claim 18 recites: A living biological matrix comprising a spore-like cell, cell fragments, lipids, and polysaccharides.

It is noted that the Examiner should be aware that the first of applicants' patents on spore-like cells and methods of obtaining such cells, have issued as U.S. Patent No. 7,060,492 "Isolation of Spore-Like Cells From Tissues Exposed to Extreme Conditions" Charles A. Vacanti

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and Martin P. Vacanti. This patent claims a method of isolating a population of spore-like cells. These cells are described in this application as published at paragraph 16.

The '404 patent does not disclose spore like cells. The '404 patent describes mesenchymal cells and other cell types, none of which are spore like. See col. 3, lines 1-7.

The '404 patent does not disclose a biological matrix comprising cells and cell debris. The '404 patent discloses cells within a polymeric matrix. See col. 3, line 49 to col. 9, line 12. Although the polymer may be a natural material such as fibrin, this is not cell debris or fragments.

There is no disclosure in the '404 patent of disrupting cells to produce cell debris. Cellular debris is formed by lysing cells – killing the cells. In contrast, the '404 patent specifically teaches that one wants the cells to attach, proliferate and form functional tissue. There is no process that would result in cell death, much less retention of dead cellular material.

The '610 patent is similar to the '404 patent in that it relates to tissue engineering. As described in the application, the matrices are seeded with cells. These are living cells, not dead or lysed cells and there is no cellular debris or fragments, nor are there spore-like cells. Neither mesenchymal nor parenchymal cells are spore like cells.

The “digestion” is to digest the tissue, not the cells, with collagenase, which degrades the extracellular matrix so that the tissue dissociates into the individual cells.

Blood does not contain cellular debris.


In summary, neither the '404 nor the '610 patent discloses the subject matter of claim 18, drawn to a biological matrix comprising a spore-like cell, cell fragments, lipids, and

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polysaccharides, nor the subject matter of claims dependent thereon, much less the subject matter of claim 24 wherein the matrix is produced by (a) obtaining a cell sample; (b) disrupting the cell sample to create a mixture containing cells and cellular debris; (c) culturing the mixture, retaining the cellular debris, in culture medium for a time and under conditions sufficient to form a biological matrix in vitro; and (d) removing the biological matrix from the culture medium, and claims dependent thereon.

Allowance of all claims 1-33 is earnestly solicited.

Respectfully submitted,



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